

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/016,752
Filing Date	October 30, 2001
First Named Inventor	Ramy Lidor-Hadas et al.
Art Unit	1625
Examiner Name	Taylor V. Oh
Attorney Docket Number	1662/55002

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
[Signature]		4,739,072	04-19-1988	Oxford et al.	
		4,783,478	11-08-1988	Wootton et al.	
		4,835,173	05-30-1989	Tyers	
		4,957,609	09-18-1990	Godfrey et al.	
		4,983,621	01-08-1991	Bunce et al.	
		5,478,949	12-28-1995	Bod et al.	
		5,629,333	05-13-1997	Young	
		5,712,302	01-27-1998	Young	
		5,854,270	12-29-1998	Gambhir	
		5,962,494	10-05-1999	Young	
		6,063,802	05-16-2000	Winterborn	
		6,388,091	05-14-2002	Lee et al.	
		2004/0019093	01-29-2004	Aronhime et al.	
		2005/0020655	01-27-2005	Molnar et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
[Signature]		EP 0 276 559 B1	08-03-1998	Tyers		
		EP 0 415 522 B1	03-06-1990	Collin		
		WO 02/36558 A2 (U.S. equivalent 2002/0107275)	05-10-2002	Lidor-Hadas et al.		
		WO 02/055492 A2 (U.S. equivalent 2002/0115707)	07-18-2002	Lidor-Hadas et al.		
		WO 03/090730 A1	11-06-2003	Ndzie et al.		

Examiner  
Signature

[Signature]

Date  
Considered

4/11/06

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/016,752
		Filing Date	October 30, 2001
		First Named Inventor	Ramy Lidor-Hadas et al.
		Art Unit	1625
		Examiner Name	Taylor V. Oh
		Attorney Docket Number	1662/55002
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
20		Pirttimäki, J., et al. "The Transformation of Anhydrate and Hydrate Forms of Caffeine at 100% RH and 0% RH, <i>European Journal of Pharmaceutical Sciences</i> , 1994, Vol. 1, pp. 203-208.	
		Iida, H., et al. "Intramolecular Cyclization of Enaminones Involving Arylpalladium Complexes. Synthesis of Carbazoles" <i>J. Org. Chem.</i> 1980, Vol. 45, pp. 2938-2942.	
		European Pharmacopoeia 4.4, Ondansetron Hydrochloride Dihydrate* 2003, pp. 3489-91.	
		Harry G. Brittain (Ed.) (1999) "Polymorphism in Pharmaceutical Solids" <i>Drugs and the Pharmaceutical Sciences</i> Vol. 95, pp. 183-226, Marcel Dekker, Inc. New York, New York.	
		Bym, S.R., et al. (Ed.) (1999) "Solid-State Chemistry of Drugs" Second Edition, pp. 59-67, SSCI, Inc. West Lafayette, Indiana.	
		Bym, S.R., et al. (Ed.) (1982) "Solid-State Chemistry of Drugs" pp. 6-7, Academic Press, New York, New York.	
		Threlfall, T.L., et al. "Analysis of Organic Polymorphs" <i>The Analyst</i> , 1995, Vol. 120, pp. 2435-2460.	
		Carlless, J.E., et al. "Cortisone acetate crystals forms" <i>J. Pharm. And Pharmacology</i> , 1966, Vol. 18, pp. 190S-197S.	
		Chen, Chem Abstr., "Synthesis of Antiemetic Ondansetron" <i>Chinese J. of Pharmaceuticals</i> , 1993, 24(6), pp. 241-242 (Ch).	
		The United States Pharmacopeia (USP 27-NF22), 22 <sup>nd</sup> edition, First Supplement, April, 2004, pages 3030, 3075-3076.	
		The United States Pharmacopeia (USP 27-NF22), 22 <sup>nd</sup> edition, Second Supplement, August, 2004, pages 3234, 3283-3285.	
		The United States Pharmacopeia (USP 28-NF21), 21 <sup>st</sup> edition, The National Formulary, January, 2003, pages 1351-1352.	
		The Merck Index p. 6977 "Ondansetron", 1996.	
		Kim, M. Y, et al. "An Efficient Process of Ondansetron Synthesis" <i>Heterocycles</i> , 1997, Vol. 45, No. 10, p. 2041-2043.	

Examiner Signature		Date Considered	4/11/56
--------------------	---	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.